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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,521	02/06/2004	Michael W. Miller	IN01415K1B	6544

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
BERNHARDT, EMILY B	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/773,521	MILLER, MICHAEL W.	
	Examiner	Art Unit	
	Emily Bernhardt	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-17,19 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/6/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Consistent with parent, restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6,8-14 and 16, drawn to compounds where X=N, simple compositions and use for treating HIV, classified in class 544, subclasses such as 295,364; class 514 subclasses 252.18, 253.11, 253.13.

II. Claims 1,3-5,7-11,14 and 16, drawn to compounds where X=CH, simple compositions and use for treating HIV, classified in class 546, subclasseses such as 187,189;class 514 subclass 316,etc.

III. Claims 15,17,19 and 20, drawn to complex compositions,uses and a kit employing compounds of I and other active ingredients, for treating a variety of uses classified in class 514 , various subclasses as determined by the nature of active ingredients employed.

IV. Claims 15,17,19 and 20,drawn to complex compositions,uses and a kit employing compounds of II and other active ingredients, for treating a variety of uses classified in class 514 , various subclasses as determined by the nature of active ingredients employed.

V. Claim 18, drawn to additional uses employing compounds of I, classified in class 514, subclasses 252.18,etc.

VI. Claim 18, drawn to additional uses employing compounds of II, classified in class 514, subclass 316,etc.

If groups III or IV are elected applicants are further required to elect an active ingredient of I or II and a specific co-ingredient for a particular use. If I or II elected election of a single species is also required.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are drawn to structurally dissimilar compounds as X varies along with Q and Z such that they are separately classified, require separate literature searches. Art which may render or anticipate compounds of one group would not necessarily do the same for the remaining in view of the structural dissimilarity of I vs II as a whole.

Groups III and IV are independent and distinct from I and II since the simple uses may be old or obvious while the complex combination of ingredients in III and IV may be patentable due to superior or new properties (synergistic effects) not present in the single, active ingredient of I or II. Within groups III and IV there are more than one invention as the claims recite multiple combinations which require independent searches and separate consideration for compliance with 35 USC 112.

Inventions I/II and V/VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case more than one use is being claimed as evident from the many recited in claim 18.

During a telephone conversation with Ms. Magatti on 5/19/04 a provisional election was made with right of traverse to prosecute the invention of V, claim 18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-17, 19-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

As claim 18 is dependent on a nonelected claim it needs to be placed in independent form to conform to the restriction requirement.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Scope of compounds and uses are not adequately enabled for the following reasons:

Scope of "isomers" and "heteroaryl" as well as the plethora of functional groups permitted at various locations in the claim is not adequately enabled. For isomers, the term reads on all such compounds of the same weight and formula regardless of complexity and dissimilarity to what is positively recited for which there is no sufficient enabling disclosure by way of examples or starting material sources. For heteroaryl, specification describes rings that have as many as 12 atoms in any array ,both fused and unfused, which can be present at almost every available position in formula I and have a multitude of substituents thereon including boron,silyl,urea,carbamoyl,more heteroaryls,etc. Applicants provide no assurance that such a class of derivatives will have the minimum activity needed to practice the invention. Applicants' limited data reported on p.34 of the specification shows as much as a 10,000 fold variation for compounds closer in structure to themselves than to remaining claimed genus. Note In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. Also note the structural requirements taught by Tagat (cited by applicants) on p.2144 in related piperazine compounds that are selective,active CCR5 antagonists. Thus, the criteria for enablement as set out in In re Wands cited in MPEP 2164.01(a),August 2000 edition has been not met given the breadth of the claims, the level of

unpredictability in the art (very structure-sensitive) and the lack of direction (i.e. working examples) provided as to what other compounds might work as a selective CCR5 antagonist.

With regard to uses being claimed in 18, while references cited in the specification and cited on the PTO-1449 may implicate CCR5 antagonism in treating arthritis (but not clearly to other inflammatory disorders), note Wang a very recent publication being provided herewith, states that the "relative contribution made by individual chemokine receptors to the progression of synovitis is not fully known." Also with regard to MS, note article being provided entitled "Update on Multiple Sclerosis Research" discusses an attempt to link the CCR5 receptor to the disease by studying a particular mutation and it was found that "no significant association.... to MS, severity of MS or lesion pattern." See p.39. Also in the following paragraph it is stated: "...no robust gene linkages related to the prevalence or prognosis have been identified." . With regard to respiratory diseases note that Owen does not include the CCR5 receptor as part of the chemokine family implicated for treating such diseases. Only organ transplantaion rejection appears to be reasonably correlated to the CCR5 receptor based on studies reported by Fischereder and Vincenti .

The disclosure is objected to because of the following informalities: Status of parent needs to be updated in the specification on p.1.

Appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is (571) 272-0664.

If attempts to reach the examiner by phone are unsuccessful, the supervisor for AU 1624, Dr. Mukund Shah, can be reached at (571)272-0674.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

EMILY BERNHARDT

PRIMARY EXAMINER

Group 1600